REMARKS

I. Preliminary Remarks

The foregoing amendment is in the revised amendment format as provided in 1267 OG 106 (25 February 2003). Accordingly, the provisions of 37 C.F.R. § 1.21, requiring submission of clean and marked-up versions of the replacement paragraphs and claims, are waived. For the Examiner's convenience, attached as Appendix A is a copy of the pending claims after entry of the foregoing amendment.

In paragraph 4 of the Action, the Examiner stated that the color drawings submitted on November 9, 2001 are only acceptable for examination purposes if the appropriate petition and fee are submitted. Attached herewith as Appendix A is a petition under 37 C.F.R. §1.84(a)(2) and § 1.84(b)(2) requesting acceptance of the color photographs previously filed (Figs. 10, 11, 17 and 18). Also submitted herewith is a check for the $130 fee pursuant to 37 C.F.R. § 1.17(h) and three copies of the color photographs originally submitted on November 9, 2001. The figures submitted herewith are identical to those filed previously and do not include new matter.

In paragraph 5 of the Action, the Examiner objected to the specification. In particular, the abstract was subject to objection because the first sentence was incomplete. The foregoing amendment provides a replacement abstract to be substituted at page 189 of the specification. In addition, the Examiner objected to the blank spaces within the specification. The foregoing amendments to the specification add the ATCC accession numbers at pages 8, 151 and 154. These additions do not constitute new matter as each deposit was specifically identified in the application as filed. *See In re Lundak*, 773 F.2d 1216, 227 U.S.P.Q. 90 (CAFC 1985). Also at page 8, the identities of clones containing cDNA inserts corresponding to SEQ ID NOS: 1, 4 and 6 were inadvertently listed incorrectly. This typographical error is corrected in the foregoing amendment. The application number of a co-owned U.S. Patent Application identified by its attorney docket number in the application as filed, is also inserted by the foregoing amendment. The foregoing amendment also capitalized the trademark "BLUESCRIPT" at specification page 69, as required by the Examiner, and corrected a typographical error at page 158. These amendments do not add new matter.

New claims 90-92 each recite an isolated nucleic acid molecule that is at least 90% identical to the sequence of the nucleic acid molecule of claim 1. Support for the recitation "nucleic acids that are 90% identical" can be found at specification page 36, line 26 through page 37, line 6. New claims 93-95 each recite an isolated nucleic acid molecule that hybridizes to the complement of the nucleic acid molecule of claim 1 under stringent conditions. Support for the recited stringent hybridization conditions is found at specification page 34, lines 12-14.

New claims 90 and 93 are directed to an isolated nucleic acid molecule that encodes a polypeptide capable of binding an IL-17 molecule. The functional characterization of binding an IL-17 molecule is supported throughout the specification, *e.g.*, at page 154, line 1 through page 155, line 14, and in the Declaration of Shuqian Jing, Ph.D., under 37 C.F.R. § 1.132, submitted herewith. New claims 91 and 94 are each directed to an isolated nucleic acid molecule that induces inflammation. The experiments described in Examples 8-12 demonstrate that the IL-17 receptor like polypeptide induces inflammation in transgenic mice through binding of its ligand, IL-17E (see specification page 166, lines 17-22). New claims 93 and 95 are each directed to an isolated nucleic acid molecule that induces myelopoiesis. The experiments described in Examples 9-12 demonstrate that the IL-17 receptor like polypeptide induces myelopoiesis in transgenic mice through binding of its ligand, IL-17E (see specification page 166, lines 17-22).

New claim 96 is directed to an isolated nucleic acid molecule encoding a polypeptide fragment that comprises any one of amino acids 14-292 of SEQ ID NO: 2, amino acids 14-350 of SEQ ID NO: 5 or amino acids 1-175 of SEQ ID NO: 7, wherein the polypeptide fragment is capable of binding an IL-17 molecule. A variety of these polypeptide fragments are disclosed in the application as filed. Polypeptide fragments containing a truncation of the carboxy terminus are supported in the specification at page 22, line 30 to page 23, line 3. Soluble polypeptide fragments that lack the transmembrane domain are supported in the specification at page 23, lines 15-22. The extracellular sequences of SEQ ID NO: 2 (amino acids 14-292) and SEQ ID NO: 5 (amino acids 14-350), characteristic of some soluble polypeptide fragments, are set out at page 17, lines 29-30 and in Figure 7. Polypeptide fragments which retain the ability to bind an IL-17 molecule are supported at page 23, lines 22-25.

II. Priority Claim

In paragraph 2 of the Action, the Examiner objected to the priority claim on page 1 of the specification, which states that the present application claims the priority benefit of U.S. Provisional Patent Application Number 60/266,159, which claims the priority benefit of U.S. Provisional Patent Application Number 60/213,125. The foregoing amendment corrects this statement and the specification now states that the present application claims the priority benefit of both provisional applications. The Applicants believe that the priority claim is now proper.

III. Information Disclosure Statement

In paragraph 3 of the Action, the Examiner stated that document C1 listed on the information disclosure statement was not considered because the relevant pages were not provided. The Applicants draw the Examiner's attention to pages 155-226 of *Practical Immunology*, Hudson *et al.* (C1), which are submitted herewith.

In addition, pursuant to the Examiner's request, the Applicants submit herewith a copy of the Supplemental Information Disclosure Statement as originally filed on March 21, 2002.

The Applicants respectfully request that the Examiner consider documents B3-B8, C1 and C3-C5 submitted herewith.

IV. The Rejections Under 35 U.S.C. §§ 102 (a) and (e) Should be Withdrawn

The Examiner rejected claims 1-12, 14, 15, 59-61, 74 and 75, asserting that these claims are anticipated under 35 U.S.C. § 102(a) by Shi *et al.,* International Patent Application Publication Number WO 99/14240. The polynucleotide sequence displayed in Figure 1 of Shi *et al.* is 86.4% identical to nucleotides 1-2015 of SEQ ID NO: 4 disclosed in the specification (100% identical to nucleotides 47-352 and 99.8% identical to nucleotides 578-2015 of SEQ ID NO: 4).

The Examiner also rejected claims 1-12, 14, 15, 59-61, 74 and 75, asserting that these claims are anticipated under 35 U.S.C. § 102(e) by Shaughnassy *et al.*, U.S. Patent Application Publication Number 2002/0102639. Shaughnassy *et al.* discloses a polynucleotide sequence that is 86.5% identical to residues 1-2015 of SEQ ID NO: 4 (99.7%

identical to nucleotides 45-352 and 99.7% identical to nucleotides 578-2015 of SEQ ID NO: 4).

These rejections have been rendered moot by amendment. The Applicants have amended claims 1, 4-8, 59-61, 74 and 75 to further distinguish the claimed invention from the disclosures of the cited documents and have canceled claims 2, 3, and 15 without prejudice. The amended claims are drawn to subject matter comprising nucleic acid molecules having sequences that are neither disclosed nor suggested by the cited documents. Therefore, the Applicants respectfully request that the rejections of claims 1, 4-8, 59-61, 74 and 75 under 35 U.S.C. §§ 102(a) and (e) over the cited references be withdrawn.

V. The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

A. The Claims are Supported by an Adequate Written Description

In paragraphs 9-11 of the Action, the Examiner rejected claims 2, 4-12, 14, 15, 59-61, 74 and 75 under 35 U.S.C. § 112, first paragraph, for failing to provide an adequate written description. Specifically, the Examiner asserted that claims 2, 4-12, 14, 15, 59-61, 74 and 75 are drawn to allelic variants of SEQ ID NOS: 1, 4 and 6 that are not adequately described. Further, the Examiner asserts that claims 7-9, 12 and 14 are also directed to fragments of SEQ ID NOS: 1, 4 and 6 that are neither structurally nor functionally characterized. In response, the Applicants submit that the rejection of claims 2, 4-12, 14, 15, 59-61, 74 and 75 under 35 U.S.C. § 112, first paragraph, for lack of written description has been rendered moot by the foregoing amendment.

Solely for the purpose of expediting prosecution, and without prejudice to the Applicants' right to seek broader claims in a continuing application, the Applicants have amended claims 1, 7 and 74 to remove "variants" and "fragments," and have canceled claim 2.

However, new claim 96 is directed to a nucleotide sequence encoding a polypeptide fragment comprising any one of amino acids 14-293 of SEQ ID NO: 2, amino acids 14-350 of SEQ ID NO: 5 or amino acids 1-175 of SEQ ID NO: 7, wherein the fragment is capable of binding an IL-17 molecule. In paragraph 11, the Examiner stated that the claimed fragments are structurally and functionally undefined and can vary in length. In response, Applicants submit that the polypeptide fragments encoded by the claimed

polypeptides are structurally defined by amino acid sequence and therefore do not indefinitely vary in length. As amended, each of the fragments recited in the claims is also functionally defined as being capable of binding an IL-17 molecule. In addition, the claimed polypeptide fragments are described in the specification. At page 23, lines 15-23, the Applicants contemplate soluble fragments which lack a transmembrane domain. Figure 7 of the specification aligns the sequences of the three IL-17 like polypeptide isoforms (SEQ ID NOS: 2, 5, and 7). The transmembrane domains of each isoform are underlined in Figure 7 and are described as amino acids 293-313 of SEQ ID NO: 2, amino acids 351-371 of SEQ ID NO: 5, and amino acids 176-196 of SEQ ID NO: 7. (See specification page 17, lines 24-26). One of skill in the art would understand from these teachings that amino acids 1-292, 1-356 and 1-175 comprise the extracellular domains of polypeptides comprising the sequences of SEQ ID NOS: 2, 5 and 7, respectively. Figure 7 also presents the signal peptide sequence in bold and indicates that it would span the first 14 amino acids. (See specification page 17, lines 27-28). The recited fragments which comprise the extracellular domains (amino acids 14-292 of SEQ ID NO: 2, amino acids 14-350 of SEQ ID NO: 5) are recited in the specification at page 17, lines 29-30. In addition, the recited polypeptide fragments of claim 1 are functionally defined by the ability to bind an IL-17 molecule. Fragments which retain the ability to bind an IL-17 molecule are described at page 23, lines 22-25, and Example 8 (see pages 154-155) is a working example demonstrating the ability of these fragments to bind IL-17E. Thus, the claimed polypeptide fragments are adequately described in the specification and structurally and functionally defined in claim 96.

The Applicants further submit that new claims 90-95 are each supported by an adequate written description in the application as filed. New claims 90-92 are directed to variants of the IL-17 receptor like polynucleotide sequences that are at least 90% identical to SEQ ID NO: 1 and that encode polypeptides that either bind an IL-17 molecule, induce inflammation or induce myelopoiesis. The structural and functional limitations recited in new claims 90-92 meet the Written Description Guidelines of the United States Patent and Trademark Office, 66 Fed. Reg. 1099 (January 30, 2001). In particular, Example 14 of the Revised Interim Written Description Guidelines Training Materials is consistent with those guidelines and teaches that a claimed variant polynucleotide that is substantially similar to a sequence taught in the specification, along with a functional limitation that the claimed variant polynucleotide encodes a variant polypeptide that exhibits an identified activity,

meets the written description requirement if the required activity can be determined from the specification. In the instant case, the claimed variants have sequences that are at least 90% identical to SEQ ID NOS: 1, 4 or 6 and therefore do not have substantial variation from the sequences taught in the specification. In addition, the claimed variants are limited to those that encode polypeptides that retain the ability to bind an IL-17 molecule, induce inflammation or induce myelopoiesis. Finally, the stringent hybridization conditions recited in new claims 93-95 are explicitly supported in the specification at page 34, lines 12-14. Accordingly, the structural and functional limitations of claims 90-95 are described in the specification in such a way as to convey to one of skill in the art that the Applicants had possession of the claimed invention at the time of filing the application.

In view of the foregoing amendments, the Applicants submit that the rejection of claims 1-12, 14, 59-61, 74 and 75 under 35 U.S.C. § 112, first paragraph, for lack of written description, has been overcome and should be withdrawn, and a rejection of new claims 90-96 on the same grounds would be improper.

B. The Claims are Enabled by the Specification

In paragraph 12 of the Action, the Examiner rejected claims 7-9, 12 and 14 under 35 U.S.C. § 112, first paragraph, for lack of enablement. In particular, the Examiner stated that the specification does not reasonably provide polynucleotides whose sequences comprise fragments of SEQ ID NOS: 1, 4 and 6. In response, the Applicants submit that these rejections have been rendered moot by the foregoing amendment.

Claims 7 was amended to effectively remove the "fragment" language upon which the Examiner based the instant rejection. Claims 8 and 9 depend from claim 7 and therefore the basis for the rejection of claims 7-9 has been rendered moot.

Claims 12 and 14 ultimately depend from claims 1 and 96. Claim 1 was amended to effectively remove the "fragment" language upon which the Examiner based the instant rejection. However, new claim 96 is directed to a nucleotide sequence encoding polypeptide fragments comprising amino acids 14-293 of SEQ ID NO: 2, amino acids 14-350 of SEQ ID NO: 5 or amino acids 1-175 of SEQ ID NO: 7, wherein the fragments are capable of binding an IL-17 molecule. These fragments are enabled by the specification and therefore claim 96 should not be rejected under 35 U.S.C. § 112, first paragraph on the same

grounds. Example 6 is a working example which describes how to make Fc-fusion proteins which comprise the extracellular domain of SEQ ID NO: 2 (amino acids 1-292) or SEQ ID NO: 5 (amino acids 1-350). (See specification pages 150-152.) These fusion proteins were disclosed as specifically inhibiting IL-17E binding to GM3104A cells, which are known to express IL-17 receptor like polypeptides. (See specification pages 154-155). As these extracellular domains comprise the claimed fragments, this data demonstrates that the claimed fragments can specifically bind IL-17E. Thus, the extracelluar fragments described in the specification are functional, and the cell binding assay described in Example 8 enables one of skill in the art to assay for IL-17 binding activity. Therefore, one of skill in the art would understand how to make and use the claimed polypeptide fragments.

The Applicants also submit that new claims 90-95 should not be rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 90-92 are directed to a polynucleotide that comprises a nucleic acid sequence that is at least 90% identical to the nucleic acid molecule of claim 1 and that encodes a polypeptide that binds an IL-17 molecule, induces inflammation or induces myelopoiesis. One of skill in the art can use the disclosed polynucleotide sequence of SEQ ID NOS: 1, 4 or 6 to identify sequences that are 90% identical to these sequences. In particular, Example 1 teaches how to identify encoding polynucleotides related to the IL-17 receptor using EST probes to screen cDNA libraries. (See specification pages 143-145.) Therefore, the starting materials are taught in the specification and the methods to identify and make the variant sequences, such as synthesizing polynucleotides and amplifying native polynucleotides, are conventional in the art. In addition, the specification provides several commercially available computer programs that are useful in determining nucleotide sequence similarity to SEQ ID NOS: 1, 4 or 6, such as GAP, BLASTN and FASTA. (See specification page 51, line 16 through page 54, line 12.) The specification also guides one of skill in the art to determine which nucleotides can be altered within a polynucleotide sequence without loss of all activity of an encoded polypeptide. (See specification page 42, line 1 through page 45, line 20.) Assays for determining the required biological activity of the polypeptides encoded by the claimed polynucleotide variants are conventional, and are also taught in the specification. In particular, Example 8 provides methods for assaying for encoded polypeptide binding to an IL-17 molecule. (See specification page 154, line 1 through page 155, line 14.) Assays to determine whether the encoded polypeptide induces inflammation and/or myelopoiesis are

provided in Example 12. (See specification page 159, line 15 through page 166, line 22.) Thus, the specification teaches one of skill in the art how to make and use the claimed polynucleotide sequences.

New claims 93-95 are directed to polynucleotides that comprise a nucleic acid sequence that hybridizes to the complement of SEQ ID NO: 1, 4 or 6 under specified stringent hybridization conditions. Techniques for identifying nucleic acids that hybridize under stringent conditions are well known in the art. The specification defines stringent hybridization conditions (specification page 34, lines 12-14), provides methods for carrying out the hybridization reactions (specification page 34, line 6 through page 35, line 21), and cites several references establishing that the techniques are well known in the art, *e.g.*, Sambrook, *et al.* and Anderson *et al.*

Claims 90 and 93 are drawn to encoded polypeptides that retain the ability to bind to an IL-17 molecule. Example 8 demonstrates that IL-17E binds the IL-17 receptor like polypeptide of the present invention. In addition, submitted herewith is a Declaration of Shuqian Jing, Ph.D. under 37 C.F.R. § 1.132 showing that the IL-17 receptor like polypeptide also binds IL-17B. See Appendix B. Taken together, this evidence establishes that IL-17 receptor like polypeptides bind multiple IL-17 molecules. Therefore, it would not require undue experimentation to determine if the claimed polynucleotides encode polypeptides that bind an IL-17 molecule.

In paragraph 13 of the Action, the Examiner rejected claims 74 and 75 under 35 U.S.C. § 112, first paragraph, asserting that the recited diagnostic agents are not enabled by the specification. In particular, the specification assertedly does not describe diseases or conditions known to be associated with the encoded protein and for which its presence or absence would be diagnostic. The Applicants traverse this rejection.

Phenotypic analyses of IL-17E over-expressing transgenic mice are described in Example 13. (See specification pages 166-169.) These analyses included detection of tissue- and lineage-specific expression of the IL-17 receptor like polypeptide, and revealed that the transgenic mice had a consistent appearance of a smaller but distinct population of granulocyte-like cells that expressed IL-17 receptor like polypeptide in the blood and bone marrow. (See Figs. 19 and 20 and specification page 168, line 32 through page 169, line 3.) The Applicants contemplated that the multi-lineage phenotype present in the transgenic mice

is indicative of a lymphoma-like phenotype. (See specification page 169, lines 19-20.) Further, the Applicants contemplated that this multi-lineage phenotype closely fits the description of an acute myelomonocytic leukemia (AML). (See specification page 16, lines 25-28.) To substantiate this conviction, Western blot analysis, as described in Example 14, demonstrated that IL-17 receptor like polypeptide is expressed in human B-lymphoblast cell lines. (See specification page 170.) According to *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Circ. 1988), the amount of direction provided by the inventor and the existence of working examples within the specification are factors to be considered when determining whether the experimentation necessary to make and use the claimed invention is undue. Thus, the specification provides objective evidence and working examples that expression of IL-17 receptor like polynucleotides may be used as a diagnostic indicator of lymphoma or AML.

In view of the foregoing amendments and remarks, the Applicants submit that the rejection of claims 7-9, 12 and 14 under 35 U.S.C. § 112, first paragraph, for lack of enablement, has been overcome and should be withdrawn, and a rejection of new claims 90-96 on the same grounds would be improper.

VI. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

In paragraph 15 of the Action, the Examiner rejected claims 1-12, 14, 15, 59-61, 74 and 75 under 35 U.S.C. § 112, second paragraph, as assertedly containing indefinite terminology. In response, the Applicants submit that the rejection has been rendered moot by amendment of the relevant claims.

Solely for the purpose of expediting prosecution, and without prejudice to the Applicants' right to seek broader claims in a continuing application, the Applicants have amended claim 1 to delete the phrases "has an activity of," and "hybridize under moderately and highly stringent conditions." Claim 7 was amended to delete the phase "an allelic variant or fragment thereof" and claim 74 was amended to delete the phase "variant or homologue thereof." In addition, the Applicants have canceled claims 2 and 3. In view of the foregoing amendments and remarks, the Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

VII. Double Patenting

In paragraph 22 of the Action, the Examiner provisionally rejected claims 1-4, 14, 15, 59-61 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-4, 10, 11, 47-49, 59 and 60 of co-pending U.S. Patent Application No. 09/723,232. Pursuant to 35 U.S.C. § 101, statutory-type double patenting can be overcome by canceling or amending the conflicting claims. The Applicants will consider canceling or amending these claims at such time as these claims are otherwise in condition for allowance.

In paragraph 23 of the Action, the Examiner rejected claims 5-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 and 10 of copending U.S. Patent Application No. 09/732,232. The Applicants acknowledge the early notice of possibly related claims in another application that may result in a double patenting rejection in the future. The Applicants will consider filing appropriate terminal disclaimer(s) upon imposition of such a rejection.

CONCLUSION

In view of the amendment and remarks made herein, the Applicants submit that claims 1, 4-12, 14, 59-61, 74-75, and 90-96 are in condition for allowance and request notification of the same. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

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Respectfully submitted,

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